

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-37, 39-44, 49-56 and 61-68 are now pending in this Application.

Claims 1, 2, 6, 9, 16-19, 30, 33, 34-37, 39-44, 57-63 and 65 have been rejected under 35 U.S.C. § 102.

Claims 1-37, 39-44, 49-56 and 61-67 have been rejected on the grounds of nonstatutory obviousness-type double patenting.

Claims 1, 30, 34, 40, 49 and 61-67 have been amended herewith. Claim 68 is new. Claims 62-67 have been amended to correct a dependency problem, them being dependent on a canceled claim.

Response to arguments and rejections

Applicants thank the Examiner for his detailed rebuttal of their arguments, but do not agree with eth Examiner's rebuttal. The claims will be re-argued below, taking into account the Examiner's rebuttal. However, as noted at the end of this response, applicants feel that an interview would advance the case to issue, and are sorry that it had not been possible to set up such an interview before filing this response, as such an interview may have assisted in avoiding the filing of an RCE, for, in applicants' opinion, at least some, if not all, of the rejections are unfounded.

35 U.S.C. § 102 Rejections

The Examiner rejected claims 34, 36 and 40 under 35 USC 102(b) as being anticipated over U.S. Patent 4,428,366 of *Findl et al* (hereinafter: *Findl*)

The Examiner rejected claims 34-36 and 40 under 35 USC 102(b) as being anticipated over U.S. Patent 5,031,617 of *Klettner et al* (hereinafter: *Klettner*).

In order to clarify the scope of the claimed invention according to the differences between *Findl* and *Klettner* and the present invention, Applicant had amended independent claim 34, emphasizing the distinctiveness of the claimed invention in the light of *Findl* and *Klettner*.

One of the distinguishing features argued is that amended claim 34 discloses an apparatus having for an implanted electrode for applying an electric field to affect a

pancreas using an implanted electrode, see FIG. 1 and related description of the present application. In contrast, *Findl* describes a non-invasive technique for applying a uniform, monopolar pulsed magnetic field using a stationary device, such as Helmholtz-type electromagnet; see Abstract and FIG. 15 of *Findl*. Such a system is not only not implantable, it is not even an electrode.

However, the Examiner responded by saying that in his opinion the electrode of *Findl* is capable of being implanted and that a recitation of an intended use must result in a structural difference.

Applicants respectfully disagree, at least for the reason that the coils used in *Findl* to apply a magnetic field are said, at col. 5, line 61 to be of a diameter of 46 cm, each. This size is too large to be implanted. Nevertheless applicants have amended the claim in two manners: first, the electrode is now termed an implantable electrode. This is a term known in the art and not an intended use. Second, the electrode structure has been clarified so as to include an implantable lead and an electrode at its end. Applicants respectfully submit these limitations are inherent in the claim. While not rejected over the art, independent claim 49 has also been amended to recite that it includes an “implantable electrode”.

Similarly, *Klettner* describes apparatus for altering human blood glucose levels by the application of electric charge that is applied by an stationary electrostatic generator, such as a Wimshurst apparatus or a Van de Graaff generator, which are stationary generators producing electrical discharges at high voltage. In particular, *Klettner* applies the electric charge through points of contact between the electrostatic generator and the body of the patient, for example the palms and the soles, see column 2, lines 40-60 and Example 1 of the present application. Such a system is not implantable. Furthermore, arguably, also *Klettner* does not include an electrode, as the static electricity does not flow through the contacts. Applicants note with response to point 4 of the Examiner’s rebuttal, that an electric field can be generated without electrodes and that the art cited is fine examples of how an electric field does not inherently need to be applied using electrodes.

However, the Examiner responded by saying that in his opinion the electrode of *Klettner* is capable of being implanted and that a recitation of an intended use must result in a structural difference.

Applicants respectfully disagree, at least for the reason that the Van de Graaff generator of *Klettner* includes (Col. 3, lines 18-44) a conducting sheet on which a patient stands and also an intra-device pulley distance of 25.5 inches, to provide a generator of 33 inches high. This size is too large to be implanted. The voltages generated by such a device are also not containable within the body, at least not by any method taught in *Klettner*.

Applicants respectfully note that these rejections are an example of a case where EVEN if the claim only has intended use limitations (and this was not the case), the art is not capable by any reasonable stretch of the imagination to be put to the described usage.

Applicants further note that a functional limitation is to be considered for the limitations it would imply on a structure. Thus, while, for example, a piece of rusted barbed wire is an electricity carrying element, it cannot be considered an implantable electrode in any reasonable usage of the term. Nevertheless, claim 34 has been amended to recite clinically acceptable implantable electrodes.

The Examiner rejected claims 1, 2, 6, 9, 16-19, 30, 33-37, 39-44, 61-63 and 65 under 35 USC 102(b) as being anticipated over U.S. Patent 5,919,216 of *Houben* et al (hereinafter: *Houben*). Claims 1, 30, 34 and 61 are independent claims.

With regard to item 6 in the Examiner's rebuttal, applicants respectfully disagree. *Houben* is NOT clearly capable of performing the functional limitation, at least for the reason the *Houben* has circuitry and/or programming that is not designed to create such a specific pulse. The Examiner's rejection is akin to saying that no functional limitation can be accepted as raw materials can always be formed into a device capable of carrying out a functional limitation. In an anticipation rejection, the Examiner is required to consider all limitations and to show how the art, as present, meets that limitation. This has not been done. Furthermore, all the locations cited by the Examiner teach, in fact, that *Houben* was unable to carry out the limitations of claim 34. In particular, *Houben* teaches that in response to eating insulin levels are increased. This is in contrast to claim 34, where such insulin levels are not increased. In *Houben* insulin levels are decreased in cases of hypoglycemia, which is not an acute response to eating as taught by *Houben*.

With regard to item 7 on the Examiner's rebuttal, applicants note that the limitation of "reduces glucose levels and does not substantially elevate insulin levels" in various forms is found in claims 1. In addition, all independent claims were also specifically argued and the Examiner did not respond to such arguments.

Regarding specifically claim 34, one of the distinguishing features argued is that the amended claim 34 recites "*wherein said circuitry reduces or prevents a substantial increase in insulin secretion during said compensation*", see for example page 63, lines 5-20 of the present application.

Though *Houben* apparently describes an implanted electrode for applying an electric field *Houben* does not describe a *circuitry that compensates for a loss of acute response to a glucose ingestion event by said pancreas and reduces or prevents a substantial increase in insulin secretion during said compensation*. Thus, there is no prima facie case of anticipation.

As commonly known in the art, a normal pancreas is expected to exhibit an acute response to an ingestion event by providing an initial bolus of insulin and to cause the shutting down of glucose secretion by the liver (albeit, at a time delay). The *circuitry* disclosed in amended claim 34 *compensates* for the loss of such an *acute response* while *reducing or preventing a substantial increase in insulin secretion*.

Houben's implanted electrode is adapted for enhancing insulin production in a patient who needs insulin treatment, see column 3, lines 10-15 of *Houben*. As such, *Houben* is adapted to stimulate earlier depolarization bursts to increase insulin production and/or to shorten the insulin-producing bursts and reduce insulin production., see the abstract, column 3, lines 32-40 and FIG. 2A of *Houben*. However, applicants respectfully submit that the Examiner did not show that *Houben* teaches or implies a *circuitry that compensates for a loss of acute response as disclosed in amended claim 34*.

As the aforementioned distinguishing feature of amended claim 34 is not described in *Houben*, either expressly or inherently, it is clear that *Houben* does not anticipate that amended claim 34.

Reference is now made to amended claim 1. Claim 1 has been amended to

more clearly state the existing limitation that blood glucose levels are significantly reduced and blood insulin levels are not significantly increased. The scope of the claim is unchanged. As *Houben* only teaches reducing glucose levels by increasing insulin levels or increasing glucose levels by reducing insulin levels, this limitation is not found in *Houben* and the Examiner has shown no prima facie case of anticipation.

Reference is now made to amended claim 30. Claim 30 is also amended to make the claim limitations regarding the electric field clearer. The scope of the claim is unchanged. Applicants respectfully submit that *Houben* does not show and the Examiner did not show in *Houben*, that blood glucose levels are reduced by applying field which does not significantly reduce blood glucose levels if they are not elevated.

Reference is now made to claim 61. The Examiner did not show in *Houben*, or elsewhere, nor did the Examiner argue that he showed, the limitation of electrifying irrespectively of blood glucose levels. Claim 61 has also been amended to recite that the electrode is attached to a muscle. This further distinguishes over *Houben*, who does not. New claim 68 has been added to provide an additional limitation not found in *Houben*.

Based on the above, Applicant asserts that the amended independent claims 1, 30, 34, and 61 are allowable main claims and that respective dependent claims are consequently allowable as being dependent on an allowable main claim.

Non-statutory Obviousness-type Double Patenting

The rejections

Claims 34-37, 39-44 and 49-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-55, 79-81 and 86 of copending Application No. 10/804,560.

Claims 1-29 and 61-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 27-30 of copending Application No. 10/570,576.

Claims 30-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-38 of copending Application No. 10/570,576. The Examiner argues that although the

conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to reduce glucose levels in an acute manner.

Claims 34-37, 39-44 and 53-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-49 of copending Application No. 10/570,576. The Examiner argues that although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use a non-excitatory electrical field when stimulating the pancreas.

Discussion

Applicant respectfully requests that the obviousness double patenting rejections be held in abeyance until the indication of allowable claims, at which point a terminal disclaimer may be filed.

The Examiner is respectfully requested to confirm that claims 3-5, 7-8, 10-15, 20-29, 31, 32, 49-56, 64, 66 and 67, which were not rejected on art, all include patentable subject matter, but for the provisional obviousness-type double patenting rejections.

Conclusion

In view of the above amendments and remarks it is respectfully submitted that claims 1-37, 39-44 49-56 and 58-67 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited. If the Examiner does not feel that the application can be allowed, prior to mailing of the Examiner's next Official Action, Applicant hereby requests an interview with the Examiner and his Supervisor to discuss the outstanding Official Action and Applicant's Amendment

Respectfully submitted,

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Enclosures:

- Petition for Extension (Three Months)
- Request for Continued Examination (RCE)